

Message

From: KIRK, ANNETTE M [AG/1005] [annette.m.kirk@monsanto.com]
Sent: 7/11/2018 4:48:26 PM
To: Schmid, Emily [Schmid.Emily@epa.gov]
Subject: FW: Acetochlor NU on alfalfa - corrected version of master label?
Attachments: 000524-00591.20180619-1-MON63410Herbicide-revised-MasterLabel-plusAlfalfaSuppl.pdf; Pg32-33-highlighted-524-591.20180619.1-MON63410Herbicide-revised-MasterLabel.pdf

Importance: High

Hello Emily,

In Reuben's absence I wanted to ask if you could help me out with this request? I sent this to Kay Montague as well, but haven't heard back. The details are below and the files are attached, but if there is anything that is not clear or that you have questions about, I'd be happy to talk with you.

The urgency for me is that I'm working right now on creating new label components to go on product production for the 2019 season that will start up very soon, and ahead of that production I need to submit updated printed labels to the States. The timing is very tight. Obviously, I would much prefer to just get a *corrected* version of this master label posted up to PPLS (under Reuben's same approval letter with same stamp date), rather than go through another amendment submission.

Please let me know what you think is possible. Feel free to call me if you like to discuss it (office and cell phone numbers are below).

Many thanks for your time and consideration of my request.

Annette

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From: KIRK, ANNETTE M [AG/1005]
Sent: Monday, June 25, 2018 10:04 AM
To: 'Baris, Reuben' <Baris.Reuben@epa.gov>
Subject: RE: Acetochlor NU on alfalfa - corrected version?
Importance: High

Hi Reuben,

I'll give you a call about this, but wanted to send it to you now to take a look at first.

I apologize for this, and if I need to send it in as an amendment then I'll go ahead and do that, but thought I would run it by you first just in case there's a chance you'd be willing to replace the one you just approved with the attached *corrected* version. I would much prefer to get this fixed now, since I'm working on drafting new printed labels to go on new product production that starts in just a couple of months – all for the 2019 season.

I realized on Friday that I had accidentally included the wrong “Replanting and Rotational Crops” section. This as you may recall is a reformatted section, and I was working on two different versions of this section, one for this master label (Warrant – encapsulated formulation) and another for our Harness (emulsifiable concentrate) master label – and I simply did a cut-and-paste from the wrong version. I left out some important crops from the “Replanting After Crop Loss” section which were on the previous version of the label, and are direct uses with tolerances so they legally could be replanted immediately, plus our field technical experts have no concern for injury. Then I should have deleted “alfalfa” from the 9-month interval under “Rotational Crops” and I missed adding alfalfa and a few other obvious crops with direct tolerances, under “Rotate the next spring to...”. I know these seem like a small things, but they are actually very big deals to our end-customers and will lead to questions and confusion if the label were printed this way.

So to clarify, attached for you to look at is a clean, corrected version of the master label that you just approved last week, with the alfalfa supplemental attached at the end. Again, this is really just correcting a simple mistake – not asking for anything that wasn’t previously approved or that shouldn’t have been changed with the approval of the new use in alfalfa. Also attached are the two extracted pages with the corrections highlighted in yellow.

I would consider “notifying” these corrections, but I’m guessing they wouldn’t meet the strict interpretation of the criteria under PR 98-10?

If I absolutely have to, I’ll submit the master with these corrections as yet another amendment, but timing for that approval would be my concern – if it goes to the end of the que and isn’t approved for several months I’ll have to “print” from what I have now, thus I’ll need a supplemental label approved along with it, with just the “Replanting and Rotational Crops” section on it, to put into the marketplace in 2019.

Very sorry again for the inconvenience here... I’d be very grateful if you would be willing to replace the version from last week with this corrected version. Let me know your thoughts.

Annette

From: KIRK, ANNETTE M [AG/1005]
Sent: Friday, June 22, 2018 1:53 PM
To: 'Baris, Reuben' <Baris.Reuben@epa.gov>
Subject: RE: Acetochlor NU on alfalfa

Hi Reuben,

Thanks so much. The version with the supplemental is there today.

All is good, except that I’m seeing now I made some errors in the new “Replanting and Rotational Crops” section ☺...primarily listing the all the correct crops for “immediate replanting”... I’m wondering if I could make these changes as a “notification” or if I need to submit fast-track amendment? Could I give you a quick call next week to discuss?

Have a good weekend.
Annette

From: Baris, Reuben [mailto:Baris.Reuben@epa.gov]
Sent: Thursday, June 21, 2018 6:36 PM
To: KIRK, ANNETTE M [AG/1005] <annette.m.kirk@monsanto.com>
Subject: Re: Acetochlor NU on alfalfa

It will be up there with the supplemental and I’m told it will replace the current version. If it doesn’t by 2pm tomorrow, please let me know.

Sent from my iPhone

On Jun 21, 2018, at 6:10 PM, KIRK, ANNETTE M [AG/1005] <annette.m.kirk@monsanto.com> wrote:

Hi Reuben,

Master label is on PPLS now, but no Supplemental label.

Annette

From: Baris, Reuben [<mailto:Baris.Reuben@epa.gov>]
Sent: Thursday, June 21, 2018 12:37 PM
To: KIRK, ANNETTE M [AG/1005] <annette.m.kirk@monsanto.com>
Subject: Re: Acetochlor NU on alfalfa

It should be live now with the supplemental. If now now by 8 pm tonight.

Sent from my iPhone

On Jun 21, 2018, at 11:54 AM, KIRK, ANNETTE M [AG/1005] <annette.m.kirk@monsanto.com> wrote:

And btw, nothing posted to PPLS yet.

From: KIRK, ANNETTE M [AG/1005]
Sent: Thursday, June 21, 2018 10:54 AM
To: 'Baris, Reuben' <Baris.Reuben@epa.gov>
Subject: RE: Acetochlor NU on alfalfa

Not a problem. Thanks for fixing. So are you going to just attach it at the end of the master label, combined as one pdf?

Annette

From: Baris, Reuben [<mailto:Baris.Reuben@epa.gov>]
Sent: Thursday, June 21, 2018 10:51 AM
To: KIRK, ANNETTE M [AG/1005] <annette.m.kirk@monsanto.com>
Subject: RE: Acetochlor NU on alfalfa

Ahh shoot. I forgot it with all the other things. I'll need to replace the label on PPLS. Should be fixed by the end of the day.

I apologize for the mix up.
Reuben

REUBEN BARIS | PRODUCT MANAGER, TEAM 25 | HERBICIDE BRANCH
U.S. ENVIRONMENTAL PROTECTION AGENCY, OFFICE OF PESTICIDE PROGRAMS | (703) 305-7356

From: KIRK, ANNETTE M [AG/1005] [<mailto:annette.m.kirk@monsanto.com>]
Sent: Thursday, June 21, 2018 11:49 AM
To: Baris, Reuben <Baris.Reuben@epa.gov>
Cc: MARVIN, THOMAS [AG/1920] <thomas.marvin@monsanto.com>; james.m.nyangulu@monsanto.com
Subject: RE: Acetochlor NU on alfalfa

Thanks Reuben.

What about the separate Supplemental label for alfalfa? I didn't see it attached.

Annette

From: Baris, Reuben [<mailto:Baris.Reuben@epa.gov>]
Sent: Thursday, June 21, 2018 10:42 AM
To: KIRK, ANNETTE M [AG/1005] <annette.m.kirk@monsanto.com>
Cc: MARVIN, THOMAS [AG/1920] <thomas.marvin@monsanto.com>; NYANGULU, JAMES M [AG/1920] <james.m.nyangulu@monsanto.com>
Subject: RE: Acetochlor NU on alfalfa

Hi Annette,
The stamped labels are attached. They should be up on PPLS shortly, unless they've already made it there.

Thanks.
Reuben

REUBEN BARIS | PRODUCT MANAGER, TEAM 25 | HERBICIDE BRANCH
U.S. ENVIRONMENTAL PROTECTION AGENCY, OFFICE OF PESTICIDE PROGRAMS | (703) 305-7356

From: KIRK, ANNETTE M [AG/1005] [<mailto:annette.m.kirk@monsanto.com>]
Sent: Thursday, June 21, 2018 7:53 AM
To: Baris, Reuben <Baris.Reuben@epa.gov>
Cc: MARVIN, THOMAS [AG/1920] <thomas.marvin@monsanto.com>; james.m.nyangulu@monsanto.com
Subject: RE: Acetochlor NU on alfalfa
Importance: High

Reuben,

Excellent news! Thanks for all your valuable comments on the labels and for prioritizing work on these to meet the PRIA due date.

Annette

From: Baris, Reuben [<mailto:Baris.Reuben@epa.gov>]
Sent: Wednesday, June 20, 2018 2:49 PM
To: KIRK, ANNETTE M [AG/1005] <annette.m.kirk@monsanto.com>
Cc: MARVIN, THOMAS [AG/1920] <thomas.marvin@monsanto.com>; NYANGULU, JAMES M [AG/1920] <james.m.nyangulu@monsanto.com>
Subject: Acetochlor NU on alfalfa

Hi Annette,
We've finished! The labels are awaiting our QAQC clearance. Once that happens I'll send you the stamped labels and the approval letters for the tech and Warrant. Thanks for sending the last revisions in a timely manner.

Also, the tolerances are live, but it will take a day or two to publish in the federal register. I believe I was alerted to June 22nd.

Thanks.

Reuben

REUBEN BARIS | PRODUCT MANAGER, TEAM 25 | HERBICIDE BRANCH
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